REMARKS

Claims 1-26 are pending. Claims 4-6, 14-16 and 18-26 are withdrawn as being drawn to a non-elected invention. Claims 3 and 9 are cancelled. Claims 1, 2, 7, 8, 10. 11, 12, 13 and 17 are currently amended.

No new matter has been added as a result of this amendment. Applicants expressly reserve the right to pursue the withdrawn subject matter in a further application that claims priority under 35 U.S.C. § 120 from this application.

Amendment and cancellation of the claims herein are not to be construed as an acquiescence to any of the rejections/objections made in any previous Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the claims as originally filed, or substantially similar claims in one or more subsequent patent applications. In view of the above amendment, applicant believes the pending application is in condition for allowance.

Objections

The Examiner has objected to claims 1 and 11 for the recitation of "originates in HHV-6." Claims 1 and 11 have been amended to recite "a recombinant HHV-viral vector" as suggested by the Examiner.

The Examiner asserts that the phrase "as represented by SEQ ID NO:" creates a broad breadth of encompassed scope. Claims have been amended to delete this phrase.

Claims 2, 3, 7-10, 12, 13 and 17 have been amended to replace "a" with "the" as suggested by the Examiner.

Claim 3 has been cancelled thereby rendering moot the objection to claim 3.

Claim 7 has been amended to delete the reference to claim 4 and the reference to RNA.

Claim 8 has been amended to replace the phrase "one kind of substance" with the term "biomolecule".

Claim 9 has been cancelled thereby rendering moot the objection to claim 9.

Claims 11-13 and 17 have been amended to replace the phrase "producing method" to "A method of producing". Dependent claims have been amended to replace the phrase "producing method" with the phrase "The method of producing."

Claim 17 has been amended to replace the phrase "and/or an umbilical cord" with the phrase "or a normal umbilical cord."

Rejections under 35 U.S.C. §112, first paragraph

Claim 3 is rejected under 35 U.S.C. §112, first paragraph because "claim 3 refers to biological deposits and to satisfy the 'how to make' requirement must specify the details of the cell line such that one of skill in the art can produce the recited cells."

Although claim 3 has been cancelled thereby rendering moot the objection, Applicants assert the following.

The Examiner alleges that the specification is objected to because the biological material recited in the claims, particularly, virus H6R28 and H6R24, is not deposited.

Applicants respectfully disagree.

It is asserted that the recombinant virus vector recited in amended claim 1 of the present application includes an exogenous nucleotide sequence located in specific regions of the full-length sequence of HHV-6 Variant B. It is noted in the attached publication (Journal of General Virology (1993), 74, 2257-2262; Exhibit A) that the recombinant virus vector of the present invention is derived from a HHV-6 Variant B.

Further, the HHV-6 Variant B, which is the starting material for the claimed vectors, is available from the ATCC (American Type Culture Collection) (see http://www.atcc.org/ATCCAdvancedCatalogSearch/ProductDetails/tabid/452/Default.aspx?ATCCNum=VR-1480&Template=animalVirology).

Applicants submit that one of skill in the art who has obtained the HHV-6 Variant B can easily produce the recombinant virus vector recited in the current claims of the present application in accordance with the descriptions presented on pages 29-32 of the English specification, as well as in the details presented in the Examples of the instant specification, for example, with the use of the primer described in Table 1.

Accordingly, it is submitted that one of skill in the art could easily make or use the vectors of the present invention based on the disclosure of the specification and the technical common knowledge at the time of filing of the present application, and can therefore obtain the recombinant virus vectors recited in the present claims. In view of the above, Applicants assert that a deposit is not required.

Claims 1, 2, 7-13 and 17 are rejected under 35 U.S.C. 112, first paragraph. The Examiner asserts that although the specification is enabling for a recombinant HHV-6 viral vector that comprises an exogenous nucleotide sequence located in an HHV-6 region selected from the group consisting of U2-U8 and U24-U25 and a method of producing this sequence, the specification allegedly fails to provide enablement for any other embodiment.

The Examiner asserts that the claims are also directed to any virus that originates in HHV-6 with an insertion into a number of regions corresponding to that of the present claims.

Applicants respectfully traverse the rejection.

Claim 1, and dependent claims thereof, have been amended to clarify both the starting material and the final material of the recombinant virus vector of the claims. Further, as described above, a person skilled in the art who has obtained the HHV-6

Variant B which is commercially available, can easily produce the recombinant virus vector recited in the pending claims of the present application in accordance with the descriptions presented on pages 29-32 of the English specification and in the Examples, more specifically, with the use of the primer described in Table 1.

Therefore, in view of the amendments to claim 1 and dependent claims thereof, Applicants assert that the claims meet the legal requirements for written description as set forth in 35 U.S.C. §112, first paragraph. Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C. §102(b)

Claims 1-3, 7-13 and 17 are rejected under 35 U.S.C. §102(b) in view of Kondo et al. (abstract, 28th International Herpesvirus Workshop, July 26-31, 2003 8.31; hereafter "Kondo").

Claims 1-3. 7-13 and 17 are rejected under 35 U.S.C. §102(b)in view of Mori et al. (US 20080226677; hereafter "Mori").

Claims 1-3, 7, 9-13 and 17 are rejected under 35 U.S.C. §102(b) in view of Hippenmeyer et al. (US 5,972,666).

Applicants respectfully traverse the rejections.

M.P.E.P § 2131 states that "[a] claim is anticipated ***only if each and every element*** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added). In this regard, Still fails to teach or suggest each and every element of the claims. Thus, the reference cannot anticipate the present invention.

The Examiner also states that Applicant cannot rely upon the foreign priority papers to overcome the rejections in view of either of Mori or Kondo because a

translation of the papers has not been made of record in accordance with 37 C.F.R. 1.55.

Attached herewith is an English translation of the Japanese application from which the current application claims priority (Exhibit B). Applicants therefore submit that the priority date of the current application is August 29, 2003. In view of the above, Applicants assert that Mori does not qualify as prior art for the current application and that Kondo does not qualify as prior art for the current application under 102(b) .

Kondo

The Examiner asserts that Kondo discloses a recombinant HHV-6 viral vector that comprises an exogenous nucleic acid encoding an enzyme as well as a marker that is located in the region between nucleotides 9041-17446 of SEQ ID No.:1.

Applicants assert that amended claim 1 requires "a recombinant HHV-viral vector that includes an exogenous nucleotide sequence within the full-length sequence of HHV-6 Variant B, located in (i) a region corresponding to the U2 through U8 region of HHV-6 or (ii) a region corresponding to the U24 and U25 regions of HHV-6, in the full-length sequence of HHV-6 Variant B.

Kondo discloses recombinant HHV-6 wherein an EGFP-puromycin gene cassette is obtained by substituting the U3-U7 gene cluster of HHV-6 with an EGFP-puromycin gene cassette. However, Kondo does not teach "a recombinant HHV-viral vector that includes an exogenous nucleotide sequence located in a region corresponding to the U2 through U8 region of HHV-6" as required by the instant claims. Further, Kondo does not teach "a recombinant HHV-viral vector that includes an exogenous nucleotide sequence in a region corresponding to the U24 and U25 region of HHV-6" as required by the instant claims.

Mori

Mori discloses a recombinant herpesvirus comprising a BAC vector sequence wherein at least part of the BAC vector sequence is inserted into a non-essential region of a herpesvirus genome.

However, Mori does not teach "a recombinant HHV-viral vector that includes an exogenous nucleotide sequence located in a region corresponding to the U2 through U8 region of HHV-6" as required by the instant claims. Further, Mori does not teach "a recombinant HHV-viral vector that includes an exogenous nucleotide sequence located in a region corresponding to the U24 and U25 region of HHV-6" as required by the instant claims.

Hippenmeyer

Hippenmeyer et al. relates to HSV-1 (herpes simplex virus type 1). In contrast, the instant claims relate to HHV-6. One of skill in the art would understand that HSV-1 is distinct from HHV-6. Although HSV-1 and HHV-6 evolved from a common ancestor, these two viruses completely differ in gene structure. The homology of the gene sequences between HSV-1 and HHV-6 is low between these two viruses. Further, the cellular tropism, which is very important in the production of a vector or for performing gene therapy, is completely different. Therefore, the technique for producing HHV-6 vectors is quite distinct from that used for production of HSV-1 vectors (see for example page 6, line 19 through page 7, line 16 of the instant specification.)

In view of all of the above, Applicants assert that the instant claims are novel in view of each of Kondo, Mori and Hippenmeyer.

In view of all of the above, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the above amendments and remarks, each of the pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is

respectfully requested to pass this application to issue. If for any reason, the Examiner does not consider this application in condition for allowance upon entry of the within Amendment, the Examiner is respectfully requested to contact the undersigned Attorney if there are any issues which can be resolved by phone prior to issuance of a further written communication.

The Commissioner is authorized to charge the extension fee and any other fees required in connection with this submission to our Deposit Account, No. 04-1105, Reference No. 64995(70904).

Respectfully submitted,

Dated: November 15, 2011

Electronic signature: /Elizabeth N. Spar/
Elizabeth N. Spar
Registration No.: 45,123
EDWARDS WILDMAN PALMER LLP
P.O. Box 55874
Boston, Massachusetts 02205